

- Appl. No. 10/623,237  
• Amdt. dated March 23, 2006  
Reply to Office Action of December 1, 2005

## REMARKS

Claim 4-5 and 34-35 have been cancelled.

The Applicants appreciate the withdrawal of most of the rejections, including that over the prior art. The only issue remaining is the rejection of claims 3, 14, 19, 26, 32 and 38 as indefinite since these claims reference figures, which allegedly makes them omnibus claims. The Applicants respectfully disagree.

“The second paragraph of § 112 requires the specification of a patent to ‘conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.’ To satisfy this requirement, the claim, read in light of the specification, must apprise those skilled in the art of the scope of the claim. Moreover, claims need not ‘be plain on their face in order to avoid condemnation for indefiniteness; rather, what [this court has] asked is that the claims be amenable to construction, however difficult that task may be.’”

*SmithKline Beecham Co. v. Apotex Co.*, 403 F.3d 1331, 1349, 74 U.S.P.Q.2d 1396, 1340 (Fed. Cir. 2005) (internal citations omitted).

A representative claim, claim 3, reads: “The crystalline form of claim 2, wherein the crystalline form has an **XRPD pattern as substantially depicted in Figure 3.**” (emphasis added)

MPEP 2173.05(r) discusses omnibus claims:

Some applications are filed with an omnibus claim which reads as follows: **A device substantially as shown and described.** This claim should be rejected under 35 U.S.C. 112, second paragraph because it is indefinite in that it fails to point out what is included or excluded by the claim language.

(emphasis added). The present claims are not omnibus claims. An omnibus claim would for example recite: “a polymorph as substantially shown and described.” The claims at issue specifically reference an XRD pattern which defines a polymorph:

X-ray powder diffraction is perhaps the “gold standard” for the qualitative determination of crystallinity. Not only can the presence of a crystalline phase be confirmed, but since each polymorph produces a unique diffraction pattern, the question of which polymorph crystallized can be addressed.

Brittain, H.G., *Polymorphism in Pharmaceutical Solids* p. 398-99 (Marcel Dekker 1999). Since one of ordinary skill in the art is familiar with XRD analysis, which is considered the “gold standard” for qualitative determination of crystallinity, these claims and their recitation of an XRD pattern apprise those skilled in the art of their scope.

Further, MPEP 2173.05(s) specifically allows for a claim to reference a figure:

Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." Ex parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted).

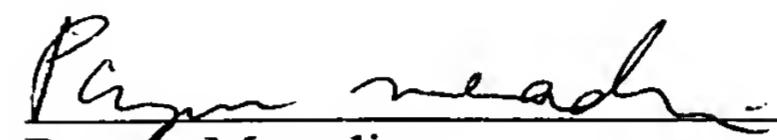
The present situation is an exceptional circumstance because there is no other way to claim an XRD pattern of a polymorphic form. The Patent Office has recognized this exceptional circumstance, and has issued many patents with claims that reference an XRD figure (*see e.g.*, Claim 78 of USP 6,500,987: “Amorphous sertraline hydrochloride, which is characterized by the x-ray diffraction pattern substantially as depicted in FIG. 2.” Or claim 3 of USP 6,767,913 “The clopidogrel hydrogensulfate of claim 2 having a powder X-ray diffraction pattern as substantially depicted in FIG. 1.”).

Applicants thus submit that the entire application is now in condition for allowance, an early notice of which would be appreciated. Should the Examiner not agree with Applicants’ position, a personal or telephonic interview is respectfully requested to discuss any remaining issues prior to the issuance of a further Office Action, and to expedite the allowance of the application.

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Respectfully Submitted,

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